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Rapid HIV Testing Update February 2003

Executive summary:

- November 7, 2002: OraQuick, a rapid HIV testing device, was approved by the Food and Drug Administration (FDA) as a Clinical Laboratory Improvement Amendment (CLIA) moderate complexity device;
- January 31, 2003: President Bush announced CLIA waiver for OraQuick, eliminating many barriers to broad implementation of rapid HIV testing;
- February 2003: OraQuick test kits available to qualified testing sites, but quantities may not initially meet demand as OraSure Technologies ramps up manufacturing;
- The California Department of Health Services, Office of AIDS (DHS/OA) is developing protocols for implementation of rapid testing in a variety of settings;
- Pilot evaluations of these protocols will proceed as device availability allows.

On November 7, 2002, the first second-generation rapid HIV test, OraQuick, was approved by the FDA for testing fingerstick blood samples for antibodies to HIV. OraQuick, made by OraSure Technologies, is highly accurate and provides results in 20 minutes. A reactive (positive for HIV antibodies) OraQuick result requires confirmation by a standard laboratory-based test – that is, a blood or oral fluid sample must be collected from the client and sent to a licensed clinical laboratory that has been approved by the Department of Health Services, Laboratory Field Services Section for further testing prior to reporting any results. A negative OraQuick result is considered definitive and does not require confirmation.

OraQuick was initially categorized as a moderate complexity test under CLIA, the federal law regulating clinical laboratory testing. This limited the use of the test to laboratory facilities and personnel who meet specific criteria. In California, most publicly-funded HIV testing clinics – especially mobile and outreach settings – do not meet these criteria. However, because the device is simple to use, does not require laboratory equipment, and contains an internal control mechanism, the device was recently "waived" under CLIA. This allows the test to be used by an HIV counselor who is trained by the Office of AIDS and working in an HIV counseling and testing site funded by the department through a local health jurisdiction, provided they are able to meet other federal and state requirements. OraSure Technologies indicated that the testing device will be available within 2-to-3 weeks to qualified testing sites. However, it is expected that demand will exceed initial supplies as the company ramps up manufacturing.

OA continues to work towards developing and evaluating protocols for the use of the OraQuick device in a variety of testing venues. These protocols will be evaluated and refined in a small sample of California testing sites qualified to conduct CLIA-waived HIV testing. This evaluation will proceed as device availability allows. On the basis of feedback from these sites, protocols will be finalized, and training and guidelines for implementing these protocols will be refined and disseminated to all qualified OA-funded sites in California.

A condition of FDA approval for this device includes restricting sales to those facilities:

- that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met; and
- where there is assurance that operators will receive and use the instructional materials.

Requirements to conduct waived rapid HIV testing in California include operating under a CLIA certificate of waiver. OA continues to work with other DHS divisions to address other requirements or restrictions that may impact access to this new technology in California.